

## **REMARKS**

### **I. Status of the Claims**

Prior to the instant Action, claims 110-113, 116-164, 167-172, 174-184, 186-189, 191-193, 195-208 and 211-218 were in the case and have been examined. Presently, claims 182 and 183 have been canceled without prejudice or disclaimer; claims 113, 116-127, 133, 136, 147, 149-152, 158-162, 172, 181, 198, 203-206, 208, 217 and 218 have been amended without prejudice or disclaimer; and claims 219-226 have been added, which are unified with the examined claims and supported by the specification.

Claims 110-113, 116-164, 167-172, 174-181, 184, 186-189, 191-193, 195-208 and 211-218 are therefore in the case. According to the revisions to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

### **II. Support for the Claims**

Support for the amended and new claims exists throughout the specification as filed and particularly in the pending claims. In light of the claims canceled to date, no fees should be due. However, any fees necessary for the introduction of the new claims should be deducted from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/4200.000200.

Claim 113 has been revised to add a second instance of "isolated", as requested by the U.S. Patent and Trademark Office ("Office"). The change is supported by this claim itself, the original, former and pending claims as a whole and the specification as filed.

Claims 116-124 have been revised to accord with independent claim 113.

Claims 125-127 have been revised to accord with independent claim 113 and to depend from claim 113.

Claims 133 and 136 have each been revised as indicated by Brian Stanton of the Office. The changes are supported by the claim themselves, the original, former and pending claims as a whole and the specification as filed.

Claim 147 has been revised to depend from claim 219.

Claims 149, 150 and 151 have been revised to reinsert "SEQ ID NO:50", recently removed from the claim and then allowed by the Office. Claim 151 has been revised to depend from claim 149, as requested by the Office. The changes are supported by the claims themselves, the original, former and pending claims as a whole and the specification as filed.

Claim 152 has been revised to replace "exhibits at least 90% identity to" with "has" in regard to the amino acid sequences of SEQ ID NO:4, SEQ ID NO:45, SEQ ID NO:47 and SEQ ID NO:50. The changes are supported by this claim itself, the original, former and pending claims as a whole and the specification as filed.

Claims 158-162 and 218 have been revised to add "isolated", as requested by the Office. The changes are supported by the claims themselves, the original, former and pending claims as a whole and the specification as filed.

Claim 172 has been revised to depend from claim 164, as requested by the Office.

Claim 181 has been revised to replace the nucleic acid hybridization language with "has the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:6". The changes are supported by this claim itself, the original, former and pending claims as a whole and the specification as filed.

Claims 198, 203-206 and 208 have been revised to change the recitations to earlier claims and the claim dependencies. The changes are supported by the claims themselves, the original, former and pending claims as a whole and the specification as filed.

Claim 217 has been revised to replace the % identity language with "has the amino acid sequence set forth in SEQ ID NO:2 or SEQ ID NO:6". The changes are supported by this claim itself, the original, former and pending claims as a whole and the specification as filed.

New claims 218-226 have been added to reflect the allowed and allowable embodiments within claims 137-148, particularly claims 144-146.

It will therefore be understood that no new matter is included within the amended or new claims.

### **III. Interview Summaries**

After the fourth, fifth and sixth Office Actions and responses, it was agreed that the examiner would telephone Applicant's representative to discuss any changes believed to be necessary for issue; particularly after the sixth Office Action, when all but two pending claims were allowed.

The seventh Action was mailed without the Office telephoning Applicant's representative.

After receipt of the seventh Action, a number of telephone interviews were held involving Examiner Steadman, SPE Achutamurthy, Office practice specialists Brian Stanton and Deborah Reynolds and Applicant's representative, Shelley Fussey. Applicant appreciates the examiners' time, during which it was agreed that many rejections would be withdrawn or could be overcome. Agreement regarding all issues was not reached.

Applicant's representative has received and reviewed the interview summaries from the Office for telephone interviews held July 27, 2004; August 03, 2004; August 10, 2004; and September 16, 2004. Applicant's representative agrees with the interview summaries from the Office, although certain important points appear to have been overlooked.

First, throughout all telephone interviews in regard to the new enablement rejection, Applicant's main point was that the newly rejected claims had been indicated as allowed or allowable since the telephone interviews with Examiner Steadman and Office practice specialist Brian Stanton beginning in March, 2003. Notably, that the sixth Office Action dated September 09, 2003 allowed all pending claims except claims 133 and 136, which were only rejected for minor clarity issues under 35 U.S.C. § 112, second paragraph. Thus, prior to the seventh Action, the written record showed that all pending claims complied with the enablement requirement of 35 U.S.C. § 112, first paragraph and that all pending claims except claims 133 and 136 were allowed.

Applicant's representative thus stressed that the claims were allowed by the Office. See, sixth Action at summary page, box 5, claims "allowed"; the continuation sheet which listed all except claims 133 and 136 as "allowed"; and the conclusion at page 3, stating that all except claims 133 and 136 are "in condition for allowance". Indeed, prior to allowance, the claims had been drafted by, or under the express supervision of, Examiner Steadman and Brian Stanton.

Therefore, Applicant's representative emphasized that the Office had not met the burden required to reject previously allowed claims. Although the enablement rejection had been re-stated and applied to narrower claims, it is essentially the same as the enablement rejection in the first Action (mailed January 05, 1999) and subsequent Actions, which had been overcome. Moreover, Applicant's representative pointed out that the citation of a single page from a 1991 review (Branden), did not meet the Office's burden to reject previously allowed claims. Applicant's representative stated that the new enablement rejection was inconsistent with the new obviousness rejection, with the Office taking the position that the art has a high degree of unpredictability on the one hand (enablement rejection) and yet one of ordinary skill in the art

could routinely clone and express P-TEFb cyclin nucleic acids on the other hand (obviousness rejection). More particularly, Applicant's representative stated that the enablement rejection was improper because the cited page was not new evidence, unavailable when the claims were allowed; was not pertinent to hybridization (*e.g.*, claim 137); and did not concern cyclins or otherwise cast doubt on the significant details in the specification.

This gives rise to the second point not reflected in the interview summaries from the Office. During a telephone interview held between Office practice specialist Brian Stanton and Applicant's representative on August 11, 2004, Brian Stanton agreed that "gaps in reasoning" existed in the enablement rejection. Referring to these "gaps in reasoning" and the withdrawal of other rejections, Brian Stanton stated, "O.K., we owe you a new office action". Prior to September 16, 2004, Applicant's representative had not received any interview summaries from the Office. Only on September 16, 2004, did Applicant's representative discover that the agreement to mail a new office action was not recorded in the Office records. Although the September 16, 2004 interview summary indicates that this is not consistent with Office policy, it was nonetheless agreed between a senior Office employee and Applicant's representative.

The third main point of difference between the interview summaries from the Office and Applicant's representative's notes is regarding the written description support for claims 133 and 136. Applicant's representative agrees that in claims reciting "fragment" in conjunction with "comprising", the fragment is to be limited to the fragment of claim 113. Indeed, this is believed to be clear, as claims 133 and 136 overtly recite "the fragment of claim 113". It was also agreed during the interview that claim language to overcome the rejection could be negotiated later. However, Applicant's representative noted the exact language suggested by Brian Stanton at that time, which is faithfully reflected in the pending claims. Moreover, Applicant points out that

only claim 133 was rejected for lack of written description, and claim 136 was not subject to rejection on this ground.

Applicant's representative also has additional notes regarding the telephone interviews. Given that the interview summaries from the Office were only received on September 16, 2004, Applicant may make additional comments of record after further review.

#### **IV. Claim Objections**

The seventh Action newly objects to certain claims. Although Applicant respectfully traverses, particularly as each of the objected claims were allowed in the sixth Action, many objections are overcome by the present response. Other objections will be overcome in conjunction with overcoming the remaining rejections applied to the same claims.

#### **V. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

The seventh Action newly rejects claims 125-127, 172 and 177 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite and for failing to particularly point out and distinctly claim the invention. Although Applicant respectfully traverses, particularly as each of the rejected claims were allowed in the sixth Action, the rejection is overcome by the present response.

#### **VI. Rejection of Claims Under 35 U.S.C. § 101**

The seventh Action further newly rejects certain claims under 35 U.S.C. § 101 as allegedly being non-statutory subject matter. Applicant respectfully traverses on various grounds, including that each of the rejected claims were allowed in the sixth Action and that other claims with the same language are evidently acceptable to the Office (*e.g.*, claim 157). In any event, the rejection is overcome by the present response.

**VII. Written Description Rejection Under 35 U.S.C. § 112, First Paragraph**

Claim 133 is further newly rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking written description support. Applicant respectfully traverses on various grounds, including that this claim was free from written description rejection in the sixth Action and that other claims with similar language are acceptable to the Office (*e.g.*, claim 134). In any event, it was agreed during the recent telephone interviews that claim language to overcome the rejection can be identified. Although a draft claim has not submitted via facsimile, the current language of claim 133 is exactly as stated by Brian Stanton in the July 27, 2004 interview. The rejection is therefore overcome.

**VIII. Enablement Rejection Under 35 U.S.C. § 112, First Paragraph**

Next, the seventh Action newly rejects independent claims 133, 136, 137, 149, 152, 157, 181, 198, 208, 217, 218, and many of the dependent claims, under 35 U.S.C. § 112, first paragraph as allegedly lacking enabling support in the specification. Applicant respectfully traverses, particularly as most of the rejected claims were allowed in the sixth Action and all rejected claims were free from enablement rejection in the sixth Action (see, sixth Action overall, including summary page, continuation sheet, conclusion and lack of any rejection under 35 U.S.C. § 112, first paragraph). Note also, the agreement reached in telephone interviews of March 2003, including the March 20, 2003 facsimile of claims that Examiner Steadman and Brian Stanton agreed were allowable.

Since the written indication of allowed claims in the sixth Action, the seventh Action states the rejection (page 6); quotes the Wands factors (with which Applicant documented compliance in response to the first Action); mis-states the breadth of the claims (page 7, note the lack of function, which is in fact recited in the rejected claims); makes conclusory statements

regarding the working examples, overlooks the teaching in the rest of the specification and the level of skill in the art (page 8); and states that there is a high level of unpredictability in the art, without providing any evidence pertinent to this particular art (page 8), and which contradicts the statements made in the obviousness rejection. None of the foregoing establish a *prima facie* enablement rejection, and particularly fail to support the rejection of allowed claims.

The seventh Action then cites a single page from a review (Branden), stating that in 1991 it was difficult to design *de novo* stable protein with specific functions (seventh Action at page 9). This one page excerpt is insufficient to support a *prima facie* enablement rejection, let alone the rejection of allowed claims. Most notably, the rejected claims all include a recitation of meaningful biological function, which can be readily tested using the assays of the specification and the art. The Office admits that the technical steps to practice the claimed invention are enabled (*e.g.*, seventh Action at page 9), but still concludes that claims with any degree of variance from the exact SEQ ID NOs are not enabled. This is not a proper conclusion under the controlling case law on the enablement requirement.

During the telephone interview of September 16, 2004, Applicant's representative stated that the ability to make variant sequences was routine in the art (*e.g.*, seventh Action at page 9), that all rejected claims recite the biological function, and the recited function can be readily tested using the assays of the specification and the art. In reply, Office practice specialist Deborah Reynolds stated that § 112, first paragraph requires that one of ordinary skill in the art can make and *use* [the claimed invention without undue experimentation in light of the present disclosure], not make and *test*. However, these requirements are the same when applied to the present claims, the practice of which requires only that a variant nucleic acid sequence be made, *e.g.*, by site-directed mutagenesis (*e.g.*, claim 149) or hybridization (*e.g.*, claim 137), *tested* to



confirm biological activity (as recited in the claims and taught in the specification), and then *used* to promote transcription (also recited in the claims).

Objective evidence of enabling support across the scope of the claims is evident in the specification as filed, which "*must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements". *In re Marzocchi & Horton*, 169 USPQ 367 (CCPA 1971), emphasis as in original. The Office, with or without the 1991 Branden excerpt, has not set forth sufficient reason to doubt the objective truth in the specification. For example, the Office has offered absolutely no evidence to suggest that one of ordinary skill in the art could not conduct nucleic acid hybridization, identify an active protein and use it in transcription, as required by the claimed invention. Strong evidence for this exists in the written record, as claims 137, 149, and others now subject to rejection, were allowed and free from enablement rejection in the sixth Action.

The enablement rejection is thus overcome and should be withdrawn.

#### IX. **Rejection of Claims Under 35 U.S.C. § 103**

Last, the seventh Action newly rejects independent claims 110, 111, 113, 128, 133, 134, 136, 137, 149, 152, 157, 181, 198, 203, 208, 217, 218, and many of the dependent claims, under 35 U.S.C. § 103(a) as allegedly being obvious over Marshall & Price, *J. Biol. Chem.*, 270:12335-12338, 1995 in view of Matsudaira, Wozney and Ausubel, three general technical review articles. Applicant respectfully traverses on various grounds, including that the rejection is in conflict with established case law from the Federal Circuit. It was agreed during the telephone interview of August 03, 2004 that the rejection was improper and would be withdrawn.

**X. Conclusion**

This is a complete response to the referenced seventh Action. In conclusion, Applicant submits that, in light of the earlier allowance and the lack of support for the new rejections, as documented herein, the present case is in condition for allowance and such favorable action is respectfully requested. Should Examiner Steadman identify any remaining informalities, a telephone call to the undersigned Applicant's representative is earnestly solicited.

Respectfully submitted,

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